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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,113	02/16/2001	Shou-Wei Ding	2577-114	2556

6449 7590 02/12/2003

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EXAMINER
HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/700,113	DING, SHOU-WEI	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears n the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *1-23 and 27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-26 and 30-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 11, filed 3 December 2002. Applicant elects Group III, claims 24-26 and 30-37, directed to transgenic plants containing a two-domain Avr gene, with traverse. Applicant traverses, saying that Groups III and IV, which the Office asserted to be related as process and product, and as distinct because the plant can be made disease-resistant by introduction of mRNA, is erroneous. What the Office intended to recite is "disease resistance by introduction of RNA", not mRNA. Plants can be made disease resistant by the introduction of RNA, as in an RNA virus, for example. Accordingly, this restriction is maintained. Claims 1-23 and 27-29 are withdrawn as belonging to a non-elected invention.

2. Claims 1-37 are pending. Claims 24-26 and 30-37 are examined in the instant application. This restriction is made FINAL.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 3, filed 16 February 2001, is attached to the instant Office action.

Claim Rejections - 35 USC § 112-second

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 24-26 and 30-37 are rejected under 35 U.S.C. 112-2nd.

In claim 24, an "inactive" cell death domain is unclear—does this mean not expressed? Or is it inactive for structural reasons?

- "Gene" is unclear because a "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Since this does not appear to be Applicant's intention, the language "a DNA of interest" is suggested. Or Applicant may recite the various components of the "gene" desired. All subsequent recitations of this language are also rejected.
- "Effecting" expression is unclear—does this mean causing? Or modifying? Or something else?

In claims 25 and 31, "derived" is unclear because this can mean the ancestry or the source. If it means the source, it is not clear what is maintained and what is left behind, of the source material. All subsequent recitations of this language are also rejected.

In claim 25, "the Avr" gene lacks antecedent basis.

In claims 26 and 32, "chimera" is a term from mythology, with unclear meaning in this claim. Does this mean recombinant? Or a physical hybrid?

In claim 30, what is a "plant-active" promoter? Is it any promoter active in a plant? Or a promoter from a plant? Or a promoter activated by a plant?

In claim 36, what is a "propagating part" of the transgenic plant?

Clarification/correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 35 and 36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 35 and 36 are drawn to seed of, or a propagating part of, the transgenic plant of claims 24, 25 or 26. Seed and propagules of the recited transgenic plant are subject to segregation of transgenes. Since no selection of the seed or propagules is recited, not all of the progeny would contain the transgene. Some would be wild-type. Therefore, these claims read on a product of nature.

Claim Rejections - 35 USC § 112, first paragraph

Written description

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 24-26 and 30-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 24 is drawn to a transgenic plant stably transformed with a two-domain Avr gene having an inactive cell death domain, operatively linked to a promoter that is capable of effecting expression of said gene in said plant when said plant is infected with a pathogenic organism.

Claim 25 is drawn to an Avr gene derived from the cucumovirus 2b gene.

Claim 26 is drawn to an Avr gene which is a chimera of the resistance domain of Tav2b and the cell death domain of the Cmv2b gene.

Claim 30 is drawn to an expression vector comprising an Avr gene having an inactive cell death domain operably linked to a plant-active promoter.

Applicants recite various functional components, but give no information on the structure(s) required for the function(s). Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111.)

Claim Rejections - 35 USC § 112-Enablement

9. Claims 24-26 and 30, 31, 33-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

- A transgenic plant stably transformed with a two-domain Avr gene wherein the Avr gene is a chimera of the resistance domain of the Tav2b gene and the cell death domain of the Cmv2b gene, where the cell death domain is operatively linked a promoter that is capable of effecting expression of the gene in the plant when the plant is infected with a pathogenic virus, where the transgenic plant is tobacco or tomato.

does not reasonably provide enablement for

- Any two-domain Avr gene, or any plant or any pathogenic organism, or the broad scope of the claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The enablement issues are: the two-domain Avr gene under control of a promoter activated by infection with a plant pathogen, any pathogenic organism, and transgenic plants other than tomato and tobacco.

The results of infecting a given plant with a given plant pathogen are unpredictable. It is known in the art that the host range of plant pathogens varies. Pathogens vary with

respect to the kinds of plants they can attack, with respect to the organs and tissues that they can infect, and with respect to the age of the organ or tissue of the plant on which they can grow (Agrios, G.N. Plant Pathology, 3rd edition, 1988, Academic Press, San Diego; p 43). Different types of plant resistance to pathogens exist. Plants are resistant to certain pathogens either because they belong to taxonomic groups that are immune to these pathogens or because they possess genes for resistance directed against the genes for virulence of the pathogen, or because for various reasons, the plants escape or tolerate infection by these pathogens (Agrios, p124).

Applicant teaches a two-domain Avr gene comprising a both the resistance domain of the Tav2b gene and the cell death domain of the Cmv2b gene, under the control of the U1 sgRNA promoter of TMV (Example 8, p28). Applicant further teaches that PR proteins are induced in wild-type tobacco following inoculation with a TMV-2vb virus.

- There is no teaching of the two-domain Avr gene under the control of a plant pathogen activated promoter.

While one skilled in the art can readily make constructs of viral gene and promoters, making a two-domain Avr gene under the control of a plant pathogen activated promoter construct such that the genes are activated upon infection of a transgenic plant comprising the 2-domain Avr gene, by a pathogenic organism, without further guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, is excessive experimentation and an undue burden.

In view of the breadth of the claims (any two-domain Avr gene, any promoter activated by infection with a pathogenic organism, any pathogenic organism—pathogenic to any organism—animal, bacterial, viral, or plant, and any transgenic plant) the lack of guidance in the specification, the lack of working examples, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

Remarks

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Group 1638
February 9, 2003

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600